

4 KIDS COLD AND COUGH NIGHTTIME NATURAL GRAPE FLAVOR- onion,anemone pulsatilla, phosphorus, goldenseal, calcium sulfide, sodium chloride, sulfur, matricaria chamomilla and arabica coffee bean liquid Hyland's

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

4 Kids Nighttime Cold & Cough Natural Grape Flavor

Relieves congestion, runny nose, sore throat, sneezing, cough, post nasal drip and occasional sleeplessness

Drug Facts

Active ingredients

Allium Cepa 6X HPUSwatery/runny nose, cold, hacking cough, painful throat

Chamomilla 6X HPUS sensitive, irritable, fussy, nocturnal occasional sleeplessness

Coffea Cruda 6X HPUS.....occasional sleeplessness, restlessness

Hepar Sulph Calc 12X HPUS..... cold, sneezing

Hydrastis 6X HPUSrattling/tickling cough, sinus congestion, dry/raw/sore throat

Natrum Muriaticum 6X HPUS...dry cough, sore throat

Phosphorus 12X HPUS.....hoarse/dry cough, nasal congestion, chest congestion

Pulsatilla 6X HPUS.....moist cough, cold, post nasal drip

Sulphur 12X HPUSchest congestion, nasal congestion, sneezing, runny nose

Uses

☐■ Temporarily relieves symptoms of common cold in children at night, including:

☐■ cough ☐ ■ runny nose ☐■ post nasal drip

☐■ sneezing ☐ ■ nasal or chest congestion

☐■ sore throat ☐■ occasional sleeplessness

Warnings

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache,

rash, nausea, or vomiting, consult a doctor promptly.

Ask a doctor before use if you have: ■ persistent or chronic cough such as smoking, asthma, chronic bronchitis or emphysema.

A persistent cough may be a sign of a serious condition. ■ cough that is accompanied by excessive phlegm (mucus).

Stop use and ask a doctor if: ■ symptoms persist for more than 7 days or worsen. ■ inflammation, fever or infection is present or develops. ■ cough tends to recur or is accompanied by a fever, rash or persistent headache.

If pregnant or breastfeeding, ask a health professional before use.

Keep out of reach of children.

Directions

□ Use as directed. □ Do not refrigerate. □ Shake well before using. □ Measure only with the dosing cup provided. □ Do not use dosing cup with other products. □ On dosing cup, mL = milliliter.

Children 2 years to under 6 years	5 mL at bedtime and every 4 hours during the night until relieved.
Children 6 years to under 12 years	10 mL at bedtime and every 4 hours during the night until relieved.
Adults and children 12 years and over	15 mL at bedtime and every 4 hours during the night until relieved.

Inactive ingredients

Citric Acid, Glycerine, Glycyrrhiza Extract, Natural Grape Flavor Purified Water, Sodium Benzoate.

Questions or comments?

(800) 624-9659

***CLAIMS BASED ON TRADITIONAL HOMEOPATHIC PRACTICE, NOT ACCEPTED MEDICAL EVIDENCE. NOT FDA EVALUATED.**

DO NOT USE IF TAMPER-EVIDENT SEAL IS BROKEN OR MISSING.

PACKAGE LABEL- 118 mL Bottle Carton

Hyland's

NATURALS™

• Kids •

Cold & Cough

NIGHTTIME

NO ALCOHOL, SUGAR,

PARABENS or DYES*

Sleeplessness

Congestion

Runny Nose

Sore Throat

Cough

Post Nasal

Drip

2-12

YEARS

NATURAL

GRAPE FLAVOR

4 FL. OZ. (118 mL)

HOMEOPATHIC



4 KIDS COLD AND COUGH NIGHTTIME NATURAL GRAPE FLAVOR

onion,anemone pulsatilla, phosphorus, goldenseal, calcium sulfide, sodium chloride, sulfur, matricaria chamomilla and arabica coffee bean liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54973-3377
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32Z N48698)	SODIUM CHLORIDE	6 [hp_X] in 1 mL
ONION (UNII: 492225Q21H) (ONION - UNII:492225Q21H)	ONION	6 [hp_X] in 1 mL
MATRICARIA CHAMOMILLA (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA - UNII:G0R4UBI2ZZ)	MATRICARIA CHAMOMILLA	6 [hp_X] in 1 mL

ARABICA COFFEE BEAN (UNII: 3SW678MX72) (ARABICA COFFEE BEAN - UNII:3SW678MX72)	ARABICA COFFEE BEAN	6 [hp_X] in 1 mL
CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)	CALCIUM SULFIDE	12 [hp_X] in 1 mL
GOLDENSEAL (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV)	GOLDENSEAL	6 [hp_X] in 1 mL
PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	12 [hp_X] in 1 mL
ANEMONE PULSATILLA (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)	ANEMONE PULSATILLA	6 [hp_X] in 1 mL
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	12 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KOOR)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-3377-1	1 in 1 CARTON	11/01/2018	
1		118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:54973-3377-2	5 mL in 1 PACKET; Type 0: Not a Combination Product	11/01/2018	
3	NDC:54973-3377-3	1 in 1 CARTON	11/01/2018	
3		148 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		11/01/2018	

Labeler - Hyland's (028570695)

Registrant - Standard Homeopathic Company (Hyland's) (008316655)

Establishment

Name	Address	ID/FEI	Business Operations
Standard Homeopathic Company		008316655	manufacture(54973-3377) , pack(54973-3377) , label(54973-3377)

Establishment

Name	Address	ID/FEI	Business Operations
Standard Homeopathic Company		080253323	manufacture(54973-3377) , pack(54973-3377) , label(54973-3377)

Establishment

Name	Address	ID/FEI	Business Operations
Applied Laboratories, Inc.		876754375	manufacture(54973-3377) , pack(54973-3377) , label(54973-3377)

Revised: 11/2021

Hyland's